May 30, 2000

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

To Whom it may concern:

We are responding to the proposed "Suitability Determination for Donors of Human Cellular and Tissue-Based Products."

The proposed requirement to freeze all Egg Donation embryos will result in a substantial reduction of live births per Egg Donation procedure. Couples having Egg Donation treatment will see a dramatic increase in the cost of having a baby. Since there are no documented cases of pathogen transmission through the Egg Donation, the current risk must be minimal.

If this proposed rule passes, it will undoubtedly be challenged in court by couples needing Egg Donation treatment and will almost certainly be struck down. We oppose the proposed Egg Donation rule and request that it be removed from the "Suitability Determination for Donors of Human Cellular and Tissue-Based Products".

Sincerely,

Francis Polansky, M.D

Richard Schmidt, M.D.

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